K051795

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Tab 4

JUL 1 4 2005

510(k) Summary

NOMAD™ Dental Portable X-ray System
June 13, 2005

1. **Company:**
   Name: Aribex, Inc.
   Address: 754 South 400 East
   Orem, UT 84651

   Official Correspondent: D. Clark Turner, PhD, CEO

   Telephone No: 801-226-5522
   FAX No: 801-434-7233

2. **Proprietary – Trade Name:** NOMAD™ Dental X-ray System
   Classification Name: Extraoral source x-ray system (per 21CFR section 872.1800)
   Common/Usual Name: Portable Dental X-ray System

3. **Predicate Device:** Portable HDX Intraoral X-ray system, (K021378), manufactured by Flow X-Ray. Literature included at Tab 11.

4. **Description:** **NOMAD™ Dental** is a portable dental x-ray system that operates on 14.4 V DC supplied by a rechargeable NiCd battery pack. The x-ray tubehead, x-ray controls, and power source are assembled into a single hand-held enclosure. The package includes spare batteries, a battery charger, and a backscatter shield.

5. **Intended Use:** The **NOMAD™ Dental** X-ray System is intended to be used by trained dentists and dental technicians as an extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects.

6. **Comparison with predicate device:**

Feature	Portable HDX Intraoral X-ray K021378	NOMAD™ Dental X-ray System
INTENDED USE:	Both systems are intended as extraoral x-ray sources to be used with intraoral image receptors for diagnostic imaging by dentists or dental technicians.	

6. Comparison (continued)

Feature	Portable HDX Intraoral X-ray K021378	NOMAD™ Dental Intraoral X-ray Source
MECHANICAL:		
Size: Body	5.5"H x 8.25" W x 8" D	13"L x 11.5"H x 5.5"W
Weight	11.7 lbs.	8.5 lbs.
Source to skin distance	20 cm	20 cm
Cone diameter	6.3 cm	6 cm
User Interface	Up-down buttons for exposure time selections with display	Up-down buttons for exposure time selection, with timer display
Backscatter radiation protection	Circular scatter shield	6.75" dia. Pb-filled acrylic plastic scatter shield
Exposure switch	On tubehead assembly, or at control panel	On tubehead assembly/ control panel
Tubehead mounting	Handheld, or on a tripod	Handheld
ELECTRICAL:		
Energy Source	120 V 50/60 Hz or 240 V 50/60 Hz AC	Rechargeable 14.4 V DC NiCd battery pack
Exposure Time	0.01 – 2.00 seconds in 0.01 increments	0.01 – 0.99 seconds in 0.01 increments
Timer Accuracy	±(10% + 1ms)	±(10% + 1ms)
mA	7 mA fixed	2.3 mA fixed
kVp	65 kVp fixed	60 kVp fixed
Waveform	Constant Potential (DC)	Constant Potential (DC)
Duty Cycle	1:60	1:60
Electrical Safety Standards	UL 2601, CSA 601-M90, EN60601-1: 1990+A1+A2	IEC60601-1, UL60601-1, EN60601-1
EMI Standards	IEC60601-1-2	IEC60601-1-2
X-RAY PERFORMANCE:		
Performance Standard	21 CFR 1020.30	21 CFR 1020.30, 1020.31 IEC60601-1-3 IEC60601-2-7

7. Conclusion:

The only significant technological difference, DC battery power versus AC line voltage, has no bearing on safety or effectiveness of the new device. Since there are no new indications for use, it is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2005

Aribex, Inc.
% Mr. Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
Medical Device Services
Underwriters Laboratories, Inc.
1655 Scott Boulevard
SANTA CLARA CA 95050-4169

Re: K051795
Trade/Device Name: NOMAD™ Dental X-ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: July 1, 2005
Received: July 5, 2005

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Tab 3

Indications For Use

510(k) Number: K051795

Device Name: NOMAD™ DENTAL X-ray System

Indications for Use: The NOMAD™ DENTAL X-ray System is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental x-ray source to produce x-ray images using intraoral image receptors.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051795

Prescription Use X OR Over-The-Counter Use ___
(per 21CFR801.109)